U.S. Const. amend.V:

> No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

21 U.S.C. §335a(a)(2):

> Mandatory Debarment — Individuals
>
> If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct —
>
> > (A) relating to the development or approval, including the process for development or approval, of any drug product, or
> >
> > (B) otherwise relating to the regulation of any drug product under this Act,
>
> the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

21 U.S.C. §335a(j)(1):

Judicial Review — In General

Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

21 C.F.R. §12.24(b)(1):

Ruling on objections and requests for hearing.

A request for a hearing will be granted if the material submitted shows the following: (1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

21 C.F.R. §12.30:

Judicial review after waiver of hearing on a regulation.

(a) A person with a right to submit objections and a request for hearing under §12.20(d) may submit objections and waive the right to a hearing. The waiver may be either an explicit statement, or a failure to request a hearing, as provided in 12.22(a)(4).

(b) If a person waives the right to a hearing, the Commissioner will rule upon the person's objections under §§12.24 through 12.28. As a matter of discretion, the Commissioner may also order a hearing on the matter under any of the provisions of this part.

(c) If the Commissioner rules adversely on a person's objection, the person may petition for judicial review in a U.S. Court of Appeals under the act.

(1) The record for judicial review is the record designated in §12.28(b)(1).

(2) The time for filing a petition for judicial review begins as of the date of publication of the Commissioner's ruling on the objections.